

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|-----------------------------------|---|--------------------------------|
| NOVO NORDISK A/S, |) | REDACTED PUBLIC VERSION |
| |) | |
| Plaintiff, |) | |
| |) | |
| v. |) | C.A. No. 05-645-SLR |
| |) | |
| SANOFI-AVENTIS, AVENTIS |) | |
| PHARMACEUTICALS INC., and AVENTIS |) | |
| PHARMA DEUTSCHLAND GMBH, |) | |
| |) | |
| Defendants. |) | |

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR
LEAVE TO FILE AN AMENDED ANSWER AND COUNTERCLAIMS**

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I. INTRODUCTION

On September 8, 2006, the Defendants (collectively “Aventis”) filed a CONSOLIDATED AND AMENDED ANSWER AND COUNTERCLAIM that included an affirmative defense of unenforceability of the patent-in-suit based on inequitable conduct and a related counterclaim seeking a declaratory judgment of unenforceability. These inequitable conduct allegations were based on the failure of the Plaintiffs (“Novo”) to disclose to the patent examiner three different references known by the defendants to be material prior art to the patent-in-suit, U.S. Patent No. 6,582,408 (the “‘408 patent”).

Through discovery in this case, Aventis has now identified a second, independent basis for inequitable conduct and therefore seeks leave to amend its answer to state the facts concerning this second basis for inequitable conduct. Attached as Exhibit A is Defendants’ Second Consolidated and Amended Answer and Counterclaims, the amended pleading Aventis seeks leave to file. Briefly stated, through its own independent investigation, Aventis discovered U.S. Patent No. 6,562,011 (the “‘011 patent”), a patent owned by Novo and closely related to the ‘408 patent. Although the ‘408 patent and the ‘011 patent issued from parallel applications, have identical inventors, and have virtually identical specifications, Novo failed to produce the ‘011 patent or its file history, notwithstanding Aventis’s numerous discovery requests for prior art and any related patents in Novo’s possession. During prosecution of the application that issued as the ‘011 patent, Novo disclosed to the examiner five prior art references that Novo withheld from the examiner considering the application for the ‘408 patent, despite their obvious materiality.

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Therefore, Aventis now seeks leave to amend

its pleadings to allege these additional instances of Novo's inequitable conduct and the unenforceability of the '408 patent, pursuant to Fed. R. Civ. P. 15(a) and 16(b).

II. BACKGROUND

A. The Scheduling Order

The deadline for amending the pleadings specified by the Court's Order of January 11, 2006 scheduling litigation matters ("Scheduling Order") was August 1, 2006 (extended by stipulation to September 1, 2006, and again extended by stipulation to September 8, 2006). Under Rule 15(a), leave to amend the pleadings "shall be freely given when justice so requires." Fed. R. Civ. P. 16(b). Rule 16(b) allows for the amendment of pleadings after the scheduled deadline "upon a showing of good cause and by leave of the district judge". Fed. R. Civ. P. 16(b). Aventis's recent discovery of the '011 patent and the prior art cited therein, all of which Novo failed to produce, **REDACTED** has revealed Novo's repeated failure to disclose highly material prior art references to the Patent Office during the prosecution of the patent-in-suit. Therefore, there is good cause to amend the pleadings at this time.

B. The '408 Patent and Its Prosecution

Novo has asserted that Aventis's OptiClik® system infringes the '408 patent, which describes a medication delivery device comprising a cartridge assembly, a dosing assembly, and a needle assembly, and a snap coupling such as a "snap lock." Since its filing, the '408 patent has always included at least one claim requiring "coupling means," the structure of which is defined by the specifications as including snap couplings, such as snap locks. During the prosecution of the '408 patent, Novo limited the coupling means to "snap locks" to overcome prior art, and the examiner cited the "snap lock" feature in his reasons for allowance as the element which rendered the claims patentable. Notice of Allowability, p. 2, Exhibit 2 to Ex. A.

C. The '011 Patent and Prosecution

The '011 patent also describes a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. '011 patent, col. 1, lines 62-65, Ex. 6. Novo's '011 and '408 patents share substantially the same disclosures (including identical drawings), name identical inventors, and each issued from non-provisional applications that Novo filed one day apart. The applications to which both the '011 and '408 patents claim priority are substantially identical and Novo filed each on the same dates. Further, the entire prosecutions of the '408 and the '011 patents ran in parallel.¹

Certain material prior art references (the "Withheld References")² were considered by the examiner during prosecution of the '011 patent. Each of the Withheld References discloses the very "snap lock" coupling that the examiner cited as his reason for allowing the claims of the '408 patent. Although highly material to the prosecution of the '408 patent, Novo failed to disclose any of the Withheld References to the Patent Office during the '408 prosecution.

D. Novo's Litigation Tactics

Although in possession of material references because of its prosecution of the related '011 patent, Novo failed to produce any of these references in response to Aventis's document requests in the present litigation. Further, Novo has previously displayed a similar unwillingness to comply with simple requests for production of obviously relevant prior art information. In a related case which was recently pending in the International Trade Commission, Novo alleged that the same accused product as in the present litigation, Aventis's OptiClik[®] system, infringed one of its patents. Aventis then expended significant effort and expense to discover invalidating prior art evidence of which Novo was in possession and failed to produce despite specific

¹ See Exhibit A, Defendants' Second Consolidated and Amended Answer and Counterclaims, ¶¶ 23-33; Began Deposition Transcript, October 3, 2006, p. 165, lines 4-8, Ex. 1 to Ex. A.

discovery requests. After Novo became aware that Aventis had obtained these references, it withdrew its claim before the ITC. Novo's litigation tactics in the present case and in the ITC case reveal a pattern of dishonesty by Novo.³

Novo's prior conduct in the related ITC litigation, coupled with Novo's failure to produce documents in the present litigation, show both Novo's unwillingness to cooperate with discovery requests and Novo's concealment of relevant, discoverable information from Aventis. Accordingly, had Novo properly cooperated in the present case with Aventis's discovery requests, Aventis would have had the necessary information to assert the attached counterclaims of inequitable conduct well before the expiration of the Scheduling Order's deadline for amendments to the pleadings.⁴ Novo's responsibility for the delay in the assertion of these counterclaims further supports Aventis's request for leave to amend the pleadings.

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² Aventis refers to the following U.S. Patent Nos.: 6,146,361; 4,936,833; 5,549,575; 5,554,125; 5,137,511. Aventis explains the contents of these references in detail in Defendants' Second Consolidated and Amended Answer and Counterclaims, Ex. A ¶ 40-50.

³ See Ex. B, pp. 2-3

⁴ For a thorough explanation of the circumstances of these events, please see the RESPONDENTS' RESPONSE TO COMPLAINANTS MOTION TO WITHDRAW AND MEMORANDUM IN SUPPORT OF MOTION FOR SANCTIONS in the Matter of CERTAIN INSULIN DELIVERY DEVICES, INCLUDING CARTRIDGES HAVING ADAPTOR TOPS, AND COMPONENTS THEREOF before the International Trade Commission, Investigation No. 337-TA-572, reproduced in part in Exhibit B.

REDACTED**III. AVENTIS HAS GOOD CAUSE TO AMEND THE PLEADINGS UNDER RULE 16(b)**

Motions for leave to amend the pleadings are to be considered under Federal Rules of Civil Procedure 15(a) and 16(b). Under Rule 15(a), a party may amend its pleading “by leave of court . . . and leave shall be freely given when justice so requires.” Fed. R. Civ. P. 15(a). The “grant or denial of an opportunity to amend is within the discretion of the District Court.” *Foman v. Davis*, 371 U.S. 178, 182 (1962). Under Rule 16(b), pleadings may be amended after the deadline of the Scheduling Order “upon a showing of good cause and by leave of the district judge.” Fed. R. Civ. P. 16(b). Rule 9(b) requires that Aventis plead its inequitable conduct defense “with particularity.” Fed. R. Civ. P. 9(b). Here, as in *Enzo Life Sciences, Inc.*, Aventis filed the present motion for leave to amend promptly after it **REDACTED** verified the information necessary to plead with particularity under Rule 9(b), namely, the failure of Novo to disclose the Withheld References during the prosecution of the ‘408 patent. *See Enzo Life Sciences, Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 488-489 (D. Del. 2003).

A. This Court Has Permitted Similar Amendments

In *Enzo Life Sciences, Inc.*, this Court granted the defendant’s motion for leave to amend the pleadings to assert an additional counterclaim of inequitable conduct after the scheduling deadline for claim amendments had passed. 270 F. Supp. 2d at 484-9. In *Enzo*, the defendants confirmed the occurrence of instances of inequitable conduct by deposing the inventors of the asserted patent. This Court stated that, because parties are required to plead inequitable conduct with particularity under Rule 9(b), the defendants were “prudent and possibly required to confirm the factual allegations through discovery” before pleading these allegations of

inequitable conduct. *Id.* at 489. Also, this Court rejected the plaintiff's claim that, because the information asserted as the basis for the inequitable conduct claims was contained within publicly available file histories, there was an undue delay in filing the amended counterclaims. *Id.* at 487. The Court held that there was no undue delay between the filing of the additional counterclaims and the depositions when the depositions took place in December and the motion to amend the claims was made in February. *Id.*

In its decision in *Enzo Life Sciences, Inc.*, this Court relied upon another factually similar case: *Advanced Cardiovascular Sys. v. Scimed Life Sys.*, 989 F. Supp. 1237 (N.D. Cal. 1997). In *Advanced Cardiovascular*, the court allowed the defendant to amend the pleadings to assert an inequitable conduct defense after the deposition testimony of the inventor and his attorney. The Court did not agree with the plaintiff, who argued that the defendant unduly delayed in filing the inequitable conduct defense because all of the information which was obtained in the depositions was available in the Patent Office file histories. Instead the court held that there was no undue delay because the defendant "was entitled to confirm factual allegations before amending to include the inequitable conduct defense." *Id.* at 1246-48.

B. Aventis Has Promptly Requested That the Pleadings Be Amended.

Similar to both *Enzo* and *Advanced Cardiovascular*, in the instant case, Aventis has confirmed that Novo inexcusably failed to disclose to the Patent Office known material prior art as required by 37 C.F.R. § 1.56(a).

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Moreover, this Court has required that inequitable conduct be pled "with particularity" pursuant to Rule 9(b). *Enzo*, 270 F. Supp. 2d at 489. Therefore, similarly to the defendants in *Enzo Life Sciences, Inc.* and *Advanced Cardiovascular*, Aventis acted appropriately to confirm

the facts underlying its inequitable conduct defense and counterclaims prior to seeking leave to amend its defenses and counterclaims.

C. Plaintiffs Will not be Prejudiced by the Filing of the Inequitable Conduct Defense at This Time

Further, there will be no prejudice to Novo by the amendment of the pleadings at this time. Novo's own failure to disclose material references to the Patent Office and its failure to produce relevant evidence in this litigation led to Aventis's need to amend the pleadings and, indeed, to the timing of the pleading. Additionally, the information needed by Novo to defend this count of inequitable conduct is in its possession already, and Novo does not need discovery from Aventis to form its defense. Finally, trial in this case is not scheduled until August 2007, giving Novo ample time to prepare its defense.

D. Aventis's Inequitable Conduct Defense is Meritorious and Is Not Futile

A court may deny leave to amend when the amendment is futile because it would not survive a motion to dismiss. *Enzo Life Sciences, Inc.*, 270 F. Supp. 2d at 489. Aventis's amended counterclaims will withstand such a motion to dismiss. When a party is charged with failure to disclose material information to the Patent Office, that party has committed inequitable conduct when (1) the information is material to the patentability of the alleged invention, (2) the knowledge of this information and its materiality is chargeable to the patent applicant, and (3) the applicant intended to mislead the Patent Office. *Id.* at 489; *Bio-Technology General Corp. v. Novo Nordisk A/S, et al.*, 2004 WL 1739722, *29 (D. Del. Aug. 3, 2004) (finding defendant Novo guilty of inequitable conduct for intentional misrepresentations to the Patent Office). Moreover, courts balance materiality with intent, and highly material withheld references require a lesser showing of intent to deceive the Patent Office. *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003).

Here, there is no dispute that attorneys at Novo prosecuting the patent-in-suit knew of or at least should have known of the Withheld References during the prosecution of the patent-in-suit, and yet Novo did not disclose the Withheld References to the Patent Office. Moreover, as discussed *supra* and in Defendants' Second Consolidated and Amended Answer and Counterclaims, the Withheld References are highly material. Therefore, the evidence in the present case supports a finding of inequitable conduct.

1. The newly discovered evidence confirms that the Withheld References were "material."

Information is "material" when it is not cumulative to information already cited or of record in the application, and (1) it establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; *or* (2) refutes, or is inconsistent with, a position the applicant takes in (i) opposing an argument of unpatentability relied on by the Office, or (ii) asserting an argument of patentability. 37 C.F.R. § 1.56(b).

The Withheld References arose during the prosecution of a related application with substantial similarity to the patent-in-suit, the '011 patent. Further, during prosecution of the patent-in-suit, the Examiner expressly relied on Novo's "snap lock" amendment and arguments distinguishing the prior art based on the "snap lock" feature in allowing the claims. Finally, as thoroughly discussed in the attached Second Consolidated and Amended Answer and Counterclaims, each of the Withheld References disclosed or taught the "snap lock" coupling means relied upon by Novo for patentability, and none of the Withheld References are cumulative of information cited to the Patent Office.

2. The newly discovered evidence shows that Novo had knowledge of the Withheld References and their materiality.

Three attorneys for Novo participated in the prosecution of both the '011 and the '408 patent. It is thus undisputable that each of those three attorneys knew or should have known of the Withheld References and their materiality at least to the prosecution of the '011 patent. As detailed in Exhibit A, the subject matter of the '011 and '408 patents is substantially similar, and each of the Withheld References discloses the claimed "snap lock" coupling of the '408 patent. Therefore, Novo was both in possession of the Withheld References and aware of the materiality of the Withheld References to the patentability of the alleged invention of the '408 patent.

3. The newly discovered evidence shows that the attorneys had an intent to deceive.

The three Novo attorneys participating in the prosecution of both the '011 and '408 patents were in possession of the Withheld References during prosecution of the patent-in-suit. These attorneys had a duty to identify any material prior art to the Patent Office. 37 C.F.R. § 1.56(a). Because these material Withheld References were not disclosed to the Patent Office, the '408 patent is unenforceable.

"[I]n order to satisfy the intent to deceive element of inequitable conduct, the conduct when viewed in light of all of the evidence, including evidence of good faith, must demonstrate sufficient culpability to require a finding of intent to deceive." *Merck & Co. v. Teva Pharms. USA*, 288 F. Supp. 2d 601, 631-32 (D. Del. 2003) (Farnan, J.). While some threshold of intent must be established, *Id.*, intent can be inferred from circumstantial evidence. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995). "Moreover, when balanced against high materiality, the showing of intent can be proportionally less." *Bristol-Myers Squibb Co.*, 326 F.3d at 1234. "Intent to mislead does not require direct evidence, and is typically inferred from the facts. . . . Further, where withheld information is material and the patentee knew or should

have know[n] of that materiality, he or she can expect to have great difficulty in establishing subjective good faith sufficient to overcome an inference of intent to mislead.” *Id.* at 1239 (internal citations omitted).

Intent to deceive can be inferred from the sum of the facts. *See Bristol-Myers Squibb Co.*, 326 F.3d at 1239. Here, the Novo attorneys were in possession of the Withheld References and knew that the Withheld References were material to the patentability of at least the '011 application. The same Novo attorneys who participated in the prosecution of the patent-in-suit failed to disclose the Withheld References during the prosecution of the patent-in-suit. Moreover, each of the Withheld References includes teachings or disclosures directed to the very claim element that the Examiner, in his Statement of Allowance of the patent-in-suit, identified as missing from the prior art. *See* Ex. A, ¶¶ 50-78. This evidence leads to the only reasonable conclusion: Novo and its attorneys intended to deceive the Examiner when they failed to disclose the highly material Withheld References.

In further support of the inference of Novo’s intent to deceive, Novo’s previous failures to disclose material prior art and its intentional misrepresentations to the Patent Office should be considered. For example, in the ITC case discussed *supra*, Novo withheld material prior art patents, some of which it owned, during prosecution of the asserted patent. Further, as in the present case, Novo did not disclose these references to Aventis despite Aventis’s specific requests for such information. Therefore, Novo’s history of inequitable conduct supports the inference of intent to deceive the Patent Office in the present case.

IV. CONCLUSION

In light of the foregoing, Aventis respectfully requests that the Court grant Aventis's motion for leave to file its second amended answer and inequitable conduct counterclaims.

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Dated: November 7, 2006
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CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of November, 2006, the attached **REDACTED**
PUBLIC VERSION OF MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS'
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